IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT KUMAR, Vijay

SERIAL NO 10/007,866 FILED December 6, 2001

TITLE BIODEGRADABLE OXIDIZED CELLULOSE ESTERS

Grp./A.U.

1623 Examiner White, E. Conf. No. 6560 Docket No. P04829US1

> SECOND SUPPLEMENTAL RULE 132 DECLARATION OF DR. VIJAY KUMAR

Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

- I. Dr. Vijay Kumar, hereby declare the following:
- I am a co-inventor of the invention set forth in Serial No. 10/007,866. 1.
- I understand that claim 36 of the application has been rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. In this regard, the Board of Patent Appeals and Interferences states that, "it has not been shown that one of ordinary skill in the art would have understood that the resulting compound of Example 1 would necessarily and inherently have the carboxylic acid content and acid number appellants attribute to it."
- The resulting compound of Example 1 inherently has a carboxylic acid content of 10.57%. Furthermore, the carboxylic content of 10.57% directly converts to an acid number of 133.9.

- 4. Claim 36 was amended to provide that the described compounds have an acid number of at least 133. Literal support for this limitation is found in Example 1, page 13, line 26 of the specification whereby it states that the starting material for synthesis of the compound in the example has a carboxylic content of approximately 14%. The resulting compound has a carboxylic content of 10.57%, which directly converts to an acid number of 133.9.
- 5. As is well understood by persons skilled in the chemical arts, acid number is the mass of potassium hydroxide (KOH) in milligrams that is required to neutralize one gram of chemical substance, here oxidized cellulose (OC). The acid number is a measure of the amount of carboxylic acid groups in a chemical compound. In a typical procedure, a known amount of sample dissolved in organic solvent is titrated with a solution of potassium hydroxide with known concentration and with phenolphthalein as a color indicator.
- 6. Once the carboxylic content of a particular compound is known, the acid number may be easily calculated by first dividing the number of grams of carboxylic acid per 100 grams of compound by the molecular weight of the carboxylic acid group (45). This quotient is then multiplied by the molecular weight of KOH (57), the product is then multiplied by 1000, then divided by 100 (g).
- 7. As stated in Example 1 of the application, the carboxylic content of OC is approximately 14%. The resulting oxidized cellulose acetate produced in this example had a carboxylic content of 10.57%, as determined experimentally by titimetry using the United States Pharmacopoeia method and modified method (previously described in paragraph 5 above). In using the modified method, titration was done with sodium hydroxide (NaOH).
- Thus, as noted in paragraph 6, to obtain the acid number of 133.9, the following formula is used:

 $\{[10.57 (g)/45] * 57\} * 1000/100 (g) = 133.9$

- 9. For all of these reasons, the application, as filed, demonstrates that the compound synthesized in Example 1 inherently has a carboxylic acid content of 10.57%, and that this carboxylic content of 10.57% directly converts to an acid number of 133.9.
- 10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date: 04/26/07

Vijay Kumar

Dr. Vijay Kumar